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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Nyle ELLIOTT et al.

Group Art Unit: **3763**

Serial No: **10/720,213**

Examiner: **Manuel A. Mendez**

Filed : **November 25, 2003**

For : **SINGLE USE CATHETER**

RESPONSE TO NOTICE OF NON-COMPLIANT AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Notice of August 9, 2006, applicant submits a substitute Brief. The Brief now states that claims 5 and 6 have been cancelled. In addition, the arguments now state that the term "one way valve" is a well known term in the art for any valve allowing flow in one direction for preventing flow in an opposite direction. Lastly, in the Statement of the Grounds of Rejection, every patent used in the pending rejection is discussed.

Regarding the term "one way port" in claim 7, an After Final Amendment is filed concurrently with the new Brief to change the term to "one way valve". This corrects an error in antecedent

basis and the Appeal Brief now states that the After Final Amendment is filed concurrently with the Appeal Brief under the appropriate section. The Appendix of Claims does not reflect this change as that, until the Amendment is entered, the amended claim 7 is not pending.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'Christopher J. McDonald', is written over a horizontal line.

Christopher J. McDonald
Reg. No. 41,533

September 6, 2006

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Attorney Docket No. A-8730.RNNCA/cat



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APPLICANT'S APPEAL BRIEF
UNDER 35 U.S.C. §41.37

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

(1) REAL PARTY IN INTEREST

The real party in interest is Oakington Corporation, the assignee of the application.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals and interferences.

(3) STATUS OF CLAIMS

Claim 1-4, 7 and 8 are pending and stand rejected. The rejection of these claims is appealed. Claims 5 and 6 are cancelled.

(4) STATUS OF AMENDMENTS

A Request for Reconsideration was filed on April 25, 2006. An Advisory Action was mailed on May 12, 2006 but did not address the arguments presented by applicant. An After Final Amendment is filed concurrently with the Brief to correct an error in antecedent basis in claim 7. The Appendix of claims does not reflect this amendment, as the amendment has not been entered.

(5) SUMMARY OF CLAIMED SUBJECT MATTER

The catheter has a balloon 26 inflated through a lumen 22. A one-way valve 32 in the inflation lumen allows inflation of the balloon, but prevents deflation. A one way valve is a well known term in the art for a valve allowing flow in one direction but preventing flow in the opposite direction. As explained in the second to last sentence on page 4 of the specification, the lumen must be cut in order to deflate the balloon. This ensures that the catheter may only be used once, which is a critical feature for hygienic reasons.

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-4, 7 and 8 rejected as obvious over US 4,547,187 (Kelly) in view of US 6,811,559 (Thorton), US 6,682,508 (Meythaler et al.), US 5,293,875 (Stone) and US 3860007 (Binard et al.). The Examiner relies upon Thorton for disclosing hydrophobic tips, Meythaler et al. for disclosing the use of filters with infusion ports and Stone for the use of hydrophobic and charcoal filters in combination with filters. The Examiner alleges that the features

taught by these patents can be combined with the disclosure of Kelly to render the claims obvious.

(7) ARGUMENT

The invention utilizes a one way valve that allows inflation of the cuff but necessitates cutting of the catheter to deflate the cuff. This is discussed at, inter alia, the last sentence of the Summary of the Invention and the last two sentences on page 4. The limitation is clearly set forth in the claims. The term "one way valve" is a well known term in the art and the prior art applied by the Examiner does not disclose this feature.

Kelly discloses a catheter having a balloon 30 which is inflated through a port having a valve 20 best seen in Figures 6 and 7. This valve is not a one-way valve as it allows inflation and deflation of the balloon as explicitly stated in column 4, lines 37-38, which states "The valve 20 can be inflated and deflated directly with a hypodermic syringe 40" The patent also discloses a valve 52 which operates in the same manner, but uses a standard Luer tip syringe without a needle. As stated in column 5, lines 43-45, when discussing valve 52, "When the balloon is to be deflated, the tip is again inserted until it opens the slit whereupon the air is released into the syringe."

Kelly does not disclose the one-way port disclosed and claimed in the application and Binard does not cure this deficiency. Binard discloses a catheter with a safety deflation means where the balloon may be deflated through the deflation movement by severing the catheter shaft adjacent its proximal end when the inflation movement is obstructed. But Binard et al. does not disclose a one-way port allowing inflation but preventing deflation through the port. Column 2, lines 39-42 discloses "..."

an inflation lumen extending between the inside of the balloon and adjacent the proximal end of the shaft, and valve means for controlling inflation and deflation of the balloon." Both Kelly and Binard et al. disclose two-way valves, allowing both inflation and deflation of the balloon and therefore no prior art, taken alone or in combination, discloses or suggests the limitations in claims 1 and 7 regarding a one-way port preventing deflation of the balloon and necessitating cutting of the catheter for removal and ensuring its single use and avoiding reuse contamination.

The distinction between a catheter with a two way valve, such as Kelly and Binard et al., and a one way valve, as the invention, is a direct result of their respective functions. The catheters disclosed by both Kelly, a cholangiography inserted in a bile duct, and Binard, a urinary drainage catheter, are designed to be reused. The catheter of the invention, a rectal catheter, cannot be adequately sterilized to be used more than once. The one way valve requires the catheter be cut for removal and makes it impossible to be reused. The use of the catheter dictates the use of a one way valve to guarantee the single use of the catheter to preserve medical hygiene. Such concerns are not present in the prior art cited by the Examiner and explain their use of a two one valve. The two way valve allows deflation of the balloon without destroying the catheter, enabling their reuse. The deflation of the balloon through the valve is explicitly disclosed by both Kelly and Binard.

The remaining patents are cited for features separate from the one way valve and do not cure the deficiencies noted above.

It is respectfully requested that the rejections be overturned and the application allowed to issue.

Respectfully submitted,

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September 6, 2006

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CLAIMS APPENDIX

1. A single use catheter, comprising:
 - a lumen having a proximate end and a distal end,
 - an inflatable cuff surrounding said lumen,
 - said lumen having a first and second conduit,
 - said first conduit in fluid communication with said inflatable cuff,
 - said second conduit in fluid communication with said proximate end of said lumen,
 - a port at an end of said first conduit, and
 - a one-way valve in said port, said one-way port allowing inflation of said cuff but not allowing deflation whereby said first conduit must be cut to deflate said cuff.
2. The single use catheter of claim 1, further comprising a syringe attached to said port.
3. The single use syringe of claim 1, further comprising a hydrophobic filter tip on said lumen proximate end.
4. The single use syringe of claim 1, further comprising a charcoal filter in said second conduit.
7. A single use catheter, comprising:
 - a first conduit having a proximate end and a distal end,
 - a second conduit having a proximate end and a distal end, said second conduit parallel to said first conduit,

an inflatable cuff surrounding said first and second conduits,

said first conduit in fluid communication with said inflatable cuff, and

a one way valve at said distal end of said first conduit, said one-way port allowing inflation of said cuff but not allowing deflation whereby said first conduit must be cut to deflate said cuff.

8. The single use syringe of claim 7, further comprising:

a port at said first conduit distal end, and

a syringe attached to said port.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None